Standardization and Harmonization of Imaging for Clinical Trials

PhRMA Perspective

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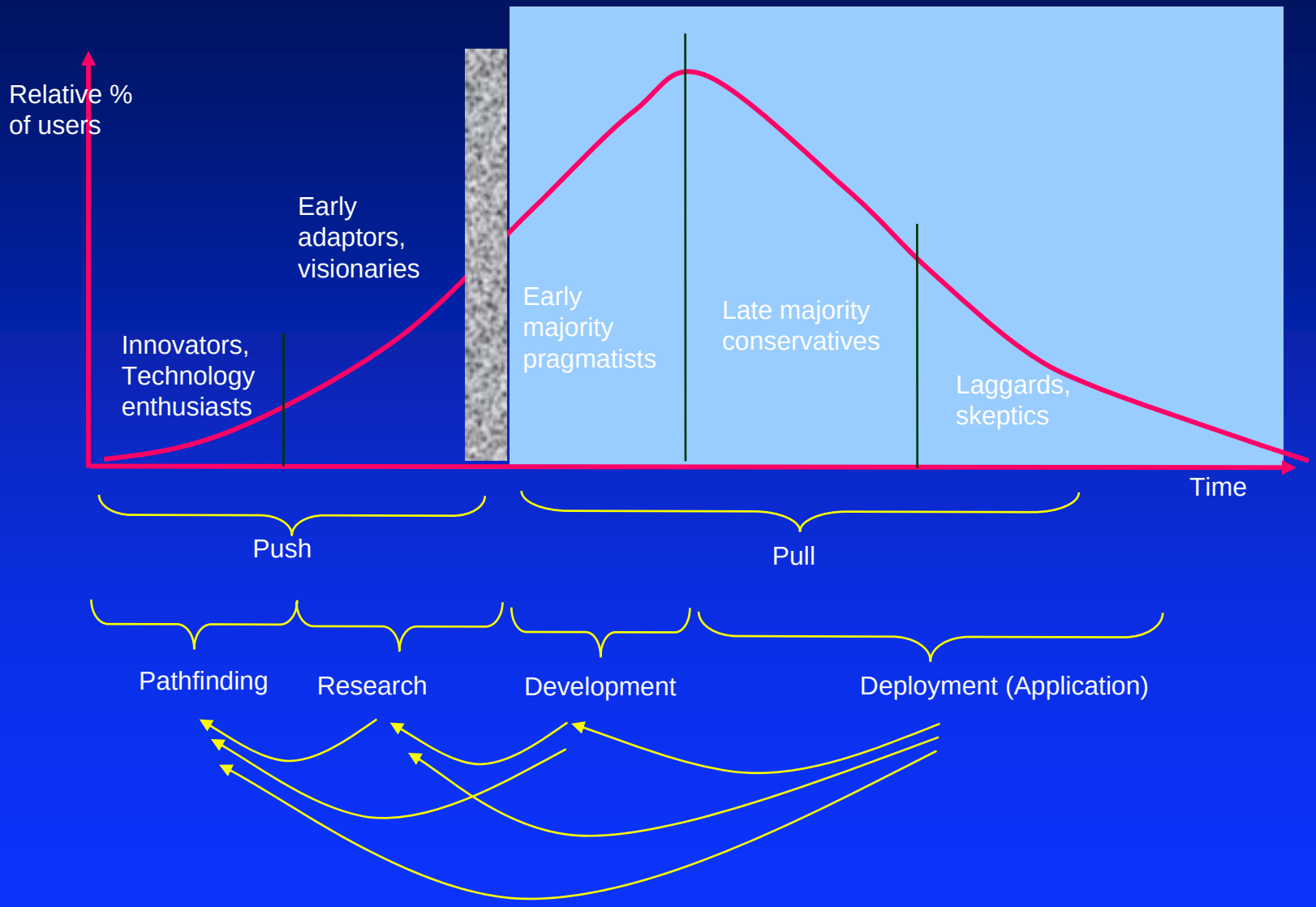
Clinical Imaging: Innovation to Deployment



Modified version of Norman model (1998: The invisible Computer)

Key Challenges

1. **Image Acquisition:**
   - High cost associated with optimal acquisition protocols
   - Insufficient plans to for re-utilization and sharing
   - Inconsistent image quality
2. **Image Analysis**:
   - Large uncoordinated investments for tool development and validation
   - Lack of standard and guidelines for pharma,
   - Subjective and sub-optimal analysis
   - Manual measures requiring large number of technicians, long delay for execution.
3. **Image Archival, Management**:
   - Lack of standards for image archival and access
   - Repeated investment across pharma, and clinical trials
   - Increased interest from regulators for access to original and analyzed images
   - Disconnect between clinical data and imaging for access and archival
   - Potential loss of opportunity for development of large clinical imaging databases to support biomarker strategy and future developments
4. **Radiolabeling of Biologiclas**:
   - Extensive safety assessment maybe required to deploy radiolabeled versions of large biologicals
   - Need for guidance for assessment of radiolabeled version of a biological

PhRMA's Perspective

Need for consensus and partnership toward developing industry standard, regulatory and clinical guidelines for harmonizing and standardizing imaging in clinical trials to manage quality, cost and time.

Four Key Questions

- A. Why do we need standards? (Impact on Quality, Cost, Speed)
- B. When do we need standardization vs. harmonization?
- C. Priority list of areas that guideline would be required: Limited, initial list of modality-disease-endpoint specific projects that are most critical for key players to begin with.
- D. Identify key partners and expected role for each of them. Partners and their roles could be project-specific.

Partners and Players